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Enclosure(s): 18 page(s) reasons for the decision (Form 2916)
Wording of Articles 106 - 108 (Form 2019)
Documents relating to the amended text
~~[-] Minutes of oral proceedings~~

to EPO postal service: 19.05.04

Registered letter with advice of delivery
EPO Form 2327 11.99CSX

1. FACTS AND SUBMISSIONS

1.1 European patent N° 0 620 720 is based on European application N° 92925128.8, filed on 12.11.1992 and claiming the priority date of 14.11.1991 from US application N° 792001. The European application was published on 26.10.1994 and the patent was granted on 18.03.1998.

The patent proprietor is :

WAKE FOREST UNIVERSITY
Winston-Salem, NC 27103, USA

1.2 Oppositions against the granted patent were filed by:

OI: MONDOMED N.V.
Middenweg 12
B-3930 Hamont - Achel (BE)
(hereinafter OI),

with letter dated 01.07.1998 and arrived at EPO on 20.07.1998. In his notice OI submitted that the patent in suit does not meet the requirements of novelty and inventive step of Art. 52(1), 54 and 56 EPC respectively, and

OII: PAUL HARTMANN A.G.
Paul-Hartmannstr. 12
D-89522 Heidenheim (DE),
(hereinafter OII)

with letter dated 16.12.1998 and arrived at EPO by fax on 16.12.1998. OII argued that the patent in suit not only is not allowable in view of Art. 52(1), 54 and 56 EPC, but also in view of Art. 52(4) since claim 1, in his opinion, comprises steps of a method of medical treatment. OII further submitted that the negative pressure applied by the device merely refers to the regulation of the pump which provides the vacuum and cannot be considered a distinguishing "technical feature" since such depressures may be obtained by regulating the operation of a normal medical suction pump.

With letter of 26.01.1999, arrived at EPO on 28.01.1999 OII introduced an amended page of his previous submissions.

1.3 Both Opponents requested oral proceedings in case of envisaged decision of maintenance of the patent in suit.

1.4 In his notice of opposition OI cited the following documents:

D1: US-A-4 969 880
D2: US-A-4 382 441
D3: US-A-3 520 300
D4: DE-C-847 475
D5: Article "Treatment Of Bone And Soft Tissue Defects In Infected Nonunion", W. Fleischmann et al., Acta Orthopaedica Belgica-Vol. 58, Suppl. I - 1992, pages 227-235
D6: Article "BWS, Gefahren und Komplikationen der Therapie", W. Fleischmann et al., OP-JOURNAL, N° 3, Jahrgang 6, Dez. 1990, Synthes GmbH, Freiburg

In his notice of opposition OII cited, besides documents D2 and D3 already cited by OI, the following documents:

D1a: WO-A-90/11795, corr. D1
D11: US-A-4 834 110
D12: US-A-3 026 874
D13: US-A-3 568 675

1.5 In a further submission dated 17.12.1998 and arrived at EPO on 18.12.1998 OI filed the following documents:

D7: Article "Wunddrainage in der Elektiv- und Notfallchirurgie: Abdominalchirurgie-Gefäßchirurgie-Extremitätenchirurgie", V. Zumtobel et al., W. Pabst Verlag, 1991, pages 4-16
D8: "Kunststoff-Taschenbuch", Seachtling, 24th Issue, pages 439, 477
D9: Article "Temporärer Hautersatz", W. Muschler, D.J. Bakker, ZFA 1989, Heft 24, paged 714-720, Sonderdrück
D10: Article "Vacuum sealing: indication, technique and results", W. Fleischmann et al., European Journal of Orthopaedic Surgery & Traumatology, (1955)-5,

pages 37-40

OI submitted also further arguments against the patentability of the claims of the patent in suit.

1.6 In his letter of 15.10.1999 the Patentee replied to the arguments of the Opponents and requested the rejection of the oppositions and the maintenance of the patent as granted.
Auxiliarily, the Patentee requested oral proceedings to be held.
The Patentee introduced into the proceedings the following document:

D14: Affidavit of Dr. Wim S. Fleischmann dated 21.01.1999 and concerning the disclosure of D5. In the Affidavit Dr. Fleischmann declares that the parts of D5 which, according to OI, could anticipate the subject-matter of claim 1 (Gent Supplement of 1992) were not divulgated during his presentation at a congress in Gent on 20-22 March 1991, but were published after the priority date of the patent in suit.

1.7 With letter of 08.03.2000 arrived at EPO on 10.03.2000 OII refused the arguments of the Patentee and maintained that the subject-matter of claim 1 of the patent in suit is either not new or does not involve an inventive step over the available prior art.

1.8 With letter of 22.09.2000 arrived at EPO on 23.09.2000 the Patentee analysed the arguments of the Opponents and concluded that the subject-matter of claim 1 of the patent in suit is allowable.

1.9 With letter of 03.05.2001 received at EPO on 05.05.2001 OI submitted a comparison between the features of claim 1 of the opposed patent and D1. OI reiterated that the subject-matter of claim 1 is not patentable in view of D1. Further documents were considered. Moreover OI submitted that the Affidavit of Dr. Fleischmann (D14) does not state that the relevant parts of the Gent Supplement were not presented in the Gent Congress of March 1991.
OI enclosed to the letter a copy of the Board of Appeal decision T 0288.

1.10 With a further submission dated 08.08.2001 and arrived at EPO on 09.08.2001 OI introduced the following document into the proceedings:

D15: Article: "Effective management of incisional and cutaneous fistulae with closed suction wound drainage" of Chariker, Mark E. et al., published in Contemporary Surgery, Vol. 34, June 1989, pages 59-63.

OI submits that this document is prejudicial for novelty or inventive step of claim 1 of the patent in suit.

1.11 With letter of 30.10.2001 arrived at EPO on 31.10.2001 OI submitted amended pages to clarify its previous letter.

1.12 Oral proceedings to be held on 29.04.2002 were summoned a first time with communication of 13.02.2002.

1.13 With letter dated 15.02.2002 arrived at EPO on 16.02.2002 OI resubmitted document D15, which apparently was not considered in the letter accompanying the first summons, together with a copy of his letter of 08.08.2001.

1.14 With fax dated 18.02.2002 and sent to EPO on 19.02.2002 the representative of OII communicated to EPO its impossibility to attend the Oral Proceedings as summoned because he had to attend on the same day to another hearing with the same Opponent.

1.15 With fax dated 01.03.2002 and sent to EPO the same day the Patentee communicated that he did not have any objection to the postponement of the hearings.

1.16 With letter of 04.03.2002, arrived at EPO on 05.03.2002 also OI communicated that he did not have any objection to the postponement of the oral proceedings.

1.17 With communication dated 14.03.2002 the EPO communicated that the summons to attend oral proceedings of 13.02.2002 were cancelled and a new date would have been appointed.

1.18 With communication of 12.08.2003 the Parties were summoned again to attend oral proceedings on 09.12.2003. In the communication enclosed to the summons the Opposition Division expressed the preliminary opinion that claim 1 of the granted patent were not new in view of the disclosure of D15.

1.19 With letter of 14.08.2003 and arrived at EPO on 18.08.2003 a third party (H.L. Milhench of R.G.C. Jenkins & C. Patent Attorneys of London) submitted observations according to Art. 115(1) against the patentability of the delivered patent. Copy of the letter was sent to the Parties as well.

1.20 With fax of 09.11.2003 and sent on the same day to EPO the Patentee filed five auxiliary sets of claims and requested the maintenance of the patent as granted or according to one of the auxiliary requests. The Patentee requested the Opposition Division to refuse the introduction of document D15 into the proceedings since it was filed after the expiration of the opposition time-limit and were not relevant. The arguments of the Opponents were further replied.
The Patentee communicated the names of the persons who intended to accompany him at the hearings.
The Patentee enclosed a copy of a page of the "Webster's Unabridged Dictionary and a copy of the Interlocutory decision of the Opposition Board concerning EP0 688 189.

1.21 With fax dated 12.11.2003 and sent on the same day to EPO, observations according Art. 115(1) were sent by H.L. Milhench of R.G.C. Jenkins & C. Patent Attorneys of London. In the submission was considered that, probably because of the overlapping dates, the Opposition Division did not have had the opportunity of consider the comments filed with his letter of 14.08.2003. Mr Milhench reiterated that the opposed patent infringes the requirements of Art. 123(2) EPC in view of the pressure range specified in claim 1. Copy of the previous submission of 14.08.2003 was also enclosed.

1.22 With letter dated 25.11.2003, arrived at EPO on 26.11.2003 the Patentee requested the Opposition Division to refuse to admit into the proceedings the grounds of opposition under Art. 100(c) or to postpone the oral proceedings. The Patentee considered that such grounds should not be admitted since they

were filed after the deadline for submissions before the Opposition Division and that there was no indication whether or not these grounds had been considered by the Opposition Division. The Patentee further considered that these new grounds were filed longtime after the expiry of the period for filing an opposition. Postponement of the proceeding was however requested to give the Patentee enough time to consider the new grounds if the Opposition Division had decided to admit these grounds in the proceedings.

1.23 With communication sent by fax on 02.12.2003 the EPO confirmed to the Patentee that the oral proceedings would have been held on 09.12.2003 and that the grounds of opposition under Art. 100(c)/123(2) EPC would have been discussed.

1.24 Oral Proceedings were held on 09.12.2003 and were attended by all the Parties. The Representative of the Patentee introduced three new request, namely auxiliary requests three to five and asked the renumbering of the previously filed auxiliary requests three to five into requests six to eight.
The Opposition Division decided to admit into the proceedings the document D15, cited by OI. The Opposition Division considered that the Parties had had enough time to consider the arguments submitted under Art. 115(1) EPC and that, in view of their relevance, said arguments have to be considered and thus introduced in the proceedings in view of Art. 114(1) EPC.
The main request and auxiliary requests 1 and 2 were rejected in view of Art. 123(2) EPC. Auxiliary requests 3 and 4 were rejected in view of Art. 52(1)/54 EPC.
During the proceedings the patentee amended auxiliary request 5 by deleting claim 20 and renumbering the following claims accordingly. The patentee amended also the description for consistency with claim 1 and to acknowledge D15.
Auxiliary request 5 as amended was considered to be allowable.

1.25 Copies of the main request and of the auxiliary requests are attached to the present decision.

2. GROUNDS FOR THE DECISION

The oppositions meet all the requirements of Art. 99(1) and 100 EPC and of Rules 1(1) and 55 of the Implementing Regulations and therefore are admissible.

Procedural matters

2.1 The Representative of the Patentee was accompanied at the haring by experts. The names and qualifications of said experts were communicated with fax of 09.11.2003.
In response to a request of OII at the beginning of the hearings, the Representative of the Patentee supplied the names of the persons who would have taken part to the discussion.
In view of the above, there is no doubt that the principles set out in the decision G 4/95 are satisfied.

Allowableness of the late submitted evidences

2.2 In their initial written submissions the Opponents argued that claim 1 of the main request (namely maintenance of the patent as granted) is not allowable since its subject-matter comprises within its scope a method of treatment of the human or animal body by therapy, Art. 52(4) EPC, and since said subject-matter is either not new or not inventive in view of the available prior art cited in the notices of oppositions or filed within the opposition delay, see points 1.4 and 1.5 above.

After the expiry of the nine months for filing an opposition OI submitted D15 and argued that this document destroys the novelty of claim 1 of the patent in suit, see his letters of 08.08.2001 and 15.02.2002. The Patentee argued in his reply of 09.11.2003 that this document should not be introduced in the proceeding since filed too late and not relevant.

The relevance of this document was discussed at the beginning of the Oral Proceedings. The parties maintained their respective opinions.
The Opposition Division decided to admit the document into the proceedings

according to Art. 114(1) since it appeared to be particularly relevant for evaluating novelty and / or inventive step of the claims of the patent in suit.

Thereafter the relevance of the objection under Art. 123(2) submitted by a third party was discussed. The Patentee submitted that Art. 115(1) EPC does not entitle a third party to introduce a new ground of opposition. The Opponents submitted that the objection was particularly relevant and should have been considered.

It appears that the lower limit given in claim 1 of the patent in suit for the negative pressure, 10.1 kPa (0.1 atm), cannot be found in the original application documents.
The Opposition Division decided therefore that, according to Art. 114(1), also this objection had to be discussed.

The Opposition Division in deciding for the introduction of document D15 and of the grounds of opposition according Art. 100(c) considered that the Parties had had enough time to evaluate the new document and the new objection.
In particular the letter of comments under Art. 115(1) of 14.08.2003 of H.L. Milhench was forwarded to the Parties, together with further comments of the same author, on 24.11.2003. Therefore the Parties have had enough time (about two weeks) to consider the objections contained in that letter. Moreover, although the EPO failed to forward immediately said letter, it appears that it was sent by its author not only to EPO but also to all the Parties at the same time.

Main Request and Auxiliary Requests 1 and 2

2.3 Art. 123(2) EPC

2.3a The Opponents submitted that the introduction of the unity "psi" (see page 4, lines 14-15 and 51-52, page 5, lines 12-13, page 6, line 10) to define the suction characteristic of the vacuum pump of the device also involves an unallowable extension of the subject-matter of the patent.
In the original application documents the unity "pound" was used. During the

examination proceeding the reference "pound" was replaced by the reference "psi" for clarity reasons.
The Patentee argued that it is typical american labour jargon (the application originates from USA) to use the term "pound" for abbreviating the unit "pound / square inch". Moreover he submitted that the skilled man would not have understood anything else than "psi" in reading the application.

The Opposition Division agrees with the arguments of the patentee. There is no doubt, in view of the technical disclosure of the original application, that the values of pressure or suction of the vacuum pump are "psi", and not "pound", which is a unity of mass.

Therefore the Opposition Division decides that this first objection under Art. 123(2) EPC has to be rejected.

2.3b Moreover the Opponents argued that the opposed patent as granted does not meet the requirements of Art. 123(2) because the range for the negative pressure "between 10.1 and 100.3 kPa (0.1 and 0.99 atm.)" specified in the characterizing portion of claim 1 is not described as such in the original documents, see paragraph 2.2 above.

In the original application documents the negative pressure to be applied on the wound ranges (preferably) from 0.01 to 0.99 atm, see page 5, lines 23-26, claims 4, 17 and 30. A most preferred range is between 0.5 to 0.8 atm.
There is no indication or hint whatsoever in said documents which may justify the limitation of 0.1 atm (10.1 kPa) for the lover limit of said pressure range.

This amendment results in the skilled person being presented with information which is not directly and unambiguously derivable from that presented in the original documents, even taking into account matter which is implicit to a person skilled in the art.
Therefore the opposed patent does not meet the requirements of Art. 123(2) EPC.

In view of that the Opposition Division decided to refuse the the main request of the Patentee, namely the maintenance of the patent as granted.

First and second auxiliary requests refer to the same unallowable lower limit for the negative pressure range, see characterizing portions of claim 1 of both requests.

Therefore also first and second auxiliary requests of the Patentee were refused for the same reasons.

Auxiliary requests 3 and 4

In response to an objection of lack of support in the originally filed documents (Art. 123(2)EPC) raised during the oral proceedings, the Patentee deleted claim 21 from the set of claims of both requests. Therefore the objection against said claims does not need to be discussed.

2.4 Rule 88, Art. 123(2) and Art. 123(3) EPC

In claim 1 of both auxiliary requests 3 and 4 the original value for the lower limit of the range of the negative pressure (namely 0.01 atm) was reintroduced. With the exception of this amendment, claim 1 of auxiliary request 3 corresponds to claim 1 of the main request.

Auxiliary request 4 differs from auxiliary request 3 in that the feature "wherein the screen means (10,24) comprises a porous, semirigid material" was added at the end of claim 1.

2.4a According to the Patentee, the replacement of the lower limit of the depressure range is simply a correction of an obvious error which is allowable under request in view of the provisions of Rule 88. Even the third party in his intervention considered that the change of the value form 0.01 atm to 0.1 atm was a consequence of a typing error.

2.4b The Opponents argued that this widening of the negative pressure range specified in claim 1 extends the protection conferred by the patent as granted and therefore it is not allowable under Art. 123(3) EPC.

Moreover the Opponents submitted that the change of the negative pressure limit from 0.01 atm to 0.1 atm was not a consequence of an error since the Patentee

conspicuously referred to the 0.1 atm limit in his letter of 21.08.1996, filed during the examination proceedings, and seems to consider that the corresponding range involves an inventive step.

2.4c According to Rule 88 EPC, an incorrect information in the claims must be objectively recognisable for the skilled man using common general knowledge from the originally filed application documents.
The correction must obvious in the sense that it is immediately evident, at least once attention is directed to the matter.
The correction should be within the limits of what the skilled person would derive directly and unambiguously from the originally filed documents, see Guidelines, C-IV,5.9.

In the present case attention to the mistake (the introduction of the 0.1 atm limit) was drown by the intervention under Art. 115(1) EPC which was filed after the letter of the Patentee referred to by the Opponents. Having regard to the originally filed application documents, it appears that there is no reference to a negative pressure limit of 0.1 atm, as pointed out also by the Opponents during the discussion of the objection under Art. 123(2), see point 2.3a above.
Moreover, the description of the patent as granted itself refers to a lower limit of 0.01 atm, see page 3, line 19.
Therefore the amendment requested by the Patentee not only complies with the requirements of Rule 88 EPC, but satisfies the requirements of Art. 123(2) EPC as well.

According to the case low of the EPO Boards of Appeal, see for instance T 438/98, a prerequisite for an amendment of a granted claim is that the granted claim properly constructed could only be interpreted as the amended claim.
This means in the present case that the amendment must both correspond to the correction of an obvious error and satisfy the requirements of Art. 123(2) EPC.
Both conditions are met, see paragraph above. Since it is evident that the invention as described in the patent should always have referred to the negative pressure range of 0.01- 0.99 atm and it had never been intended to change this range, the amendment does not contravene the requirements of Art. 123(3) EPC, see T 371/88.

Therefore the objection under Art. 123(3) against auxiliary requests 3 and 4 has to be rejected.

2.5 Art. 52(4) - Medical Treatments

The Opponents maintained the objection under Art. 52(4) EPC also against auxiliary requests 3 and 4.
In particular they submitted that maintaining or applying a negative pressure on a wound (of a human body) is a functional feature that defines a medical therapeutic treatment, such treatment being barred from patentability by Art. 52(4) EPC. The feature, according to the Opponents, is in the reality directed to the physician who should operate the apparatus to obtain the desired healing effects and thus involves a limitation on a medical action.

This opinion cannot be followed by the Opposition Division. Claim 1 is clearly directed to an apparatus and the feature referred to by the Opponents defines in functional terms a feature of the vacuum means of the apparatus, as it is clear from the wording of the claim: vacuum means for creating... The depressure range created by the vacuum means in the device refers without any doubt to the vacuum means and not to a method of healing a wound performed by a surgeon.

In view of the above the objection under Art. 52(4) against auxiliary requests 3 and 4 (and against the other requests as well) was rejected.

2.6 Art. 52(1) and 54 EPC - Novelty

The objection of lack of novelty, originally raised against the main request, was maintained by both Opponents also against the auxiliary requests 3 and 4 submitted during the oral proceedings.
The Opponents referred mainly to D15 to substantiate their objections against both requests. D1 was also considered against the novelty of the requests.

However, the Opposition Division considers D1 less relevant than D15 for

assessing novelty. This document does not really refer to a device for healing a wound by application of vacuum, but to a device to introduce and evacuate medicaments on a wound. No hint to a vacuum pressure range is to be found in or derived from the document.
Moreover, in the embodiment of fig. 1-8 the device does not comprise screen means, while in the embodiment of figs. 9 and 10 there is no permanent application of vacuum pressure. The device may be connected if desired to a suction source to evacuate fluid, not to create permanent depressure.

2.6a Novelty - Third auxiliary request

While the Opponents argued that D15 discloses in combination all of the features of claim 1 according to the third request, the Patentee submitted that the gauze described in D15 cannot be identified with the screen means of claim 1 of the request and that the "drainage" system of D15 does not correspond to an apparatus for facilitating healing of a wound. Moreover the Patentee submitted that the vacuum means of claim 1 of the third request cannot be identified with the drainage system of D15.

The Opposition Division considers that D15 completely anticipates the subject-matter of claim 1.
The device described in D15 , see page 59, right column, obviates skin damage, improves wound granulation and contraction and is effective in "decreasing the inflammatory phase of wound healing preventing eschar formation". D15 further states on page 59 that "the result is to increase the rate of repithelialization"
There is therefore no doubt whatsoever that the device of D15 is "an apparatus for facilitating the healing of a wound" as claimed in claim 1 of the request.
The "vacuum means for creating a negate pressure on the area of the skin including and surrounding the wound" is clearly defined on page 60, paragraphs 9) and 10). The "sealing means operatively associated with the vacuum means for maintaining the negative pressure on said wound by contacting the skin surrounding the wound" corresponds to the means described on page 60, paragraphs 5) to 8). The range of 60-80 mmHg (0.08-0.105 atm) of depressure comes within the negative range stated in claim 1. Finally, the screen means

specified in claim 1 are considered to correspond to the combination of the Jackson-Pratt Mini-Snyder hemovac drain and the gauze as defined on page 60, right column, and shown in figs. 1 and 2.

The consideration of the Patentee that D15 merely refers to a "continuos suction system" for drainage which does not really serves to apply vacuum to a wound cannot be followed. The document clearly refers to a depressure created in the device, which corresponds to the depressure cited in claim 1. The application of sealant, the transparent adhesive film dressing, the use of Stomahesive Paste to seal an air tight closure, see par. 5), 6), 7) on page 60 clearly and unambiguously indicate that the device maintains vacuum on the wound.
Moreover the opposed patent itself refers to the claimed device in combination with drainage effects, see page 4, lines 49-52.

The Patentee further argued that the screen means referred to in claim 1 involves difference. In particular underlined that said screen means have the purpose of preventing overgrowth of tissue, while in D15, see page 60, it is a component in the suction system.

Also this consideration cannot be followed. Claim 1, besides the definition of the purpose of the screen (preventing overgrowth of tissue) does not give any technical feature of said screen which may involve a difference with the screen formed by the gauze and the Jackson-Pratt drain described in D15. The fact that in D15 it is stated that the system therein described limits granulation and the degree of fibroplasia while in the description of the patent in suit, at the contrary, this is indicated as being a desired effect, this is not enough to decide that the simple reference to the purpose of preventig overgrowth of tissue in claim 1 may involve a difference.
Moreover decreasing the level of granulation may involve a prevention of overgrowth of tissue, insofar as the two effects may be considered to have a correlation.

Therefore the subject-matter of claim 1 of the third auxiliary request is not new and the request was rejected in view of Art. 52(1) and 54 EPC.

2.6b Novelty - Forth auxiliary request

Claim 1 of the forth auxiliary request differs from claim 1 of the third auxiliary request in that the feature "wherein the screen means (10,24) comprises a porous, semirigid material" was added at the end of the claim.

Support for such feature can be found on page 3, lines 56-57 of the granted patent and on page 8, line 7 of the original application. The amendment appears to comply with the requirements of Art.123(2) and (3) EPC.

The Opponents considered that this feature does not involve any difference against the matter of D15, the definition "semi-rigid" being unclear and vague. Moreover they considered that the drain of D15 must be porous.

The Patentee argued that in D15 the drain comprises holes and not pores, while the gauze cannot be considered a semirigid material.

The Opposition Division considers that the new features do not distinguish the subject-matter of claim 1 against D15.
Besides the fact that the definition "semi-rigid" is a relative definition, it has to be considered that the Jackson-Pratt Mini-Snyder drain of D15 cannot be "rigid" since it has to be adapted inside a wound and that, in order to perform drainage, it must however maintain a form which allows this function. Moreover the system drainage tube-gauze comes within the definition of "porous" material.

Therefore the forth auxiliary request was rejected in view of Art. 52(1) and 54 EPC.

Auxiliary request 5

2.7 Claim 1 of auxiliary request 5 differs from claim 1 of auxiliary request 3 in that the feature "in which said screen means (10,24) comprises an open-cell polymer foam" was added at the end of the claim.

This feature was taken from former claim 2, which was in consequence deleted. The remaining claims were renumbered accordingly.

During the oral proceeding the Patentee deleted claim 20 of the request to overcome an objection under Art. 123(2) EPC.

Auxiliary request 5 meets the requirements of Art. 123(2) and (3) for the same reasons given in paragraphs 2.4 to 2.4c above and meets the requrements of Art. 52(4) for the same reasons given in paragraph 2.5 above.

2.8 Novelty - Fifth auxiliary request

The Opponents argued that the disclosure of D15 is not limited to a "screen" comprising a gauze. On page 60 of said disclosure reference is made to other materials in general, like "conventional dressings" or "gauze sponges", which can be made from open cells polymers. D15 should therefore be considered to disclose, implicitly, also this feature.

The Patentee replied that the sponge gauzes do not really form part of the disclosure of D15 and that the document does not mention an "open cells polymer foam".

The Opposition Division considers that there is no mention or indication in D15 which may suggest that an open cells polymer foam may be used in the device therein disclosed instead of the gauze.

Therefore claim 1 of the auxiliary request 5 meets the requirements of Art. 52(1) EPC as regards novelty, Art. 54 EPC.

2.9 Inventive step - Fifth auxiliary request

The Opponents submitted that screens of the kind now claimed in claim 1 are disclosed in D1. In said document, in particular on page 20, lines 11-13, similar

materials are disclosed. Also the combination of the application of vacuum in combination with a screen of polymer foam should be considered to be disclosed or at least suggested in said document. The combination of this disclosure with the disclosure of D15 is, according to the Opponents, prejudicial for the inventive step of claim 1.

According to the Opposition Division, although D1 discloses screen means made of polymeric foams, there is no hint for the skilled man to combine the teachings of the two documents to arrive at the subject-matter of claim 1 of the request.

The purpose of the "screen" or intermediate layer in D1 is to absorb or to wick the fluids from the wound in order to effectively drain the wound. There is no hint in D1 that such a foam screen may be used for other purposes.
In D15, as stated above, said polymeric foam material is even not cited.
There is no hint in the available prior art documents of the use of an "open cells polymeric foams" screen, in combination with the application of vacuum, to prevent overgrowth of tissue at a wound.

In view of that claim 1 of auxiliary request 5 meets the requirements of Art. 52(1) also as regards the inventive step, art 56 EPC.

The Applicant amended the description for consistency with claim 1 of the fifth request, renumbered the claims and introduced a reference to D15.

The requested as amended was considered to be allowable.

3. DECISIONS

3.1 The Opposition Division decides that the patent can be maintained according to the fifth auxiliary request as modified during the oral proceedings.

3.2 The main request and first and second auxiliary requests are rejected since they do not meet the requirements of Art. 123(2) EPC.

3.3 Third and forth auxiliary requests are rejected since they do not meet the requirements of novelty of Art. 52(1) and 54 EPC

19. 05. 2004

Article 106
Decisions subject to appeal

(1) An appeal shall lie from decisions of the Receiving Section, Examining Divisions, Opposition Divisions and the Legal Division. It shall have suspensive effect.

(2) An appeal may be filed against the decisions of the Opposition Division even if the European patent has been surrendered or has lapsed for all the designated States.

(3) A decision which does not terminate proceedings as regards one of the parties can only be appealed together with the final decision, unless the decision allows separate appeal

(4) The apportionment of costs of opposition proceedings cannot be the sole subject of an appeal.

(5) A decision fixing the amount of costs of opposition proceedings cannot be appealed unless the amount is in excess of that laid down in the Rules relating to Fees.

Article 107
Persons entitled to appeal and to be parties to appeal proceedings

Any party to proceedings adversely affected by a decision may appeal. Any other parties to the proceedings shall be parties to the appeal proceedings as of right.

Article 108
Time limit and form of appeal

Notice of appeal must be filed in writing at the European Patent Office within **two months** after the date of notification of the decision appealed from. The notice shall not be deemed to have been filed until after the fee for appeal has been paid. Within **four months** after the date of notification of the decision, a written statement setting out the grounds of appeal must be filed.

Further information concerning the filing of an appeal

(a) The appeal is to be filed with the European Patent Office either at its seat in Munich, at its branch at The Hague or at its Berlin sub-office. The postal addresses are as follows:

(i) European Patent Office
D-80298 Munich
Germany
(Telex: 523656 epmu d)
(Fax: +49 89 2399-4465)

(ii) European Patent Office
Branch at The Hague
Patentlaan 2
Postbus 5818
NL-2280 HV Rijswijk (ZH)
Netherlands
(Telex: 31651 epo nl)
(Fax: +31 70 340-3016)

(iii) European Patent Office
Berlin sub-office
D-10958 Berlin
Germany
(Fax: +49 30 25901-840)

(b) The notice of appeal must contain the name and address of the appellant in accordance with the provisions of Rule 26(2)(c) EPC, and a **statement** identifying the decision which is impugned and the extent to which amendment or cancellation of the decision is requested (see Rule 64 EPC). The notice of appeal and any subsequent submissions stating the grounds for appeal must be signed.

(c) Notice of appeal must be **filed in writing** (typewritten or printed (Rule 36(2) EPC), by telegram, telex or fax (Rule 36(5) EPC; OJ EPO 6/89, 219-225; OJ EPO 9/89, 396)).

(d) The fee for appeal is laid down in the Rules relating to Fees. The equivalents in the national currencies in which the fee for appeal can be paid are regularly published in the Official Journal of the European Patent Office under the heading "Guidance for the payment of fees, costs and prices".

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Description

Field of the Invention

This invention relates generally to wound healing, and more specifically is directed to apparatus for treating wounds that are unlikely to heal completely under conventional methods.

Background of the Invention

The treatment of open wounds that are too large to spontaneously close has been a troublesome area for many years. Wound closure requires that epithelial and subcutaneous tissue adjacent to the wound migrate toward and eventually close the wound. Some wounds are sufficiently large or infected that they are unable to close spontaneously. In such instances, a zone of stasis, an area in which localized swelling of tissues restricts the flow of blood to these tissues, forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and accordingly is unable to close spontaneously.

The most common technique for closure of open wounds has long been the use of sutures or staples. These mechanical closure methods provide tension on the skin tissue at the wound border that encourages epithelial tissues to migrate toward the wound and cover it. While suturing and stapling of wounds is widely practiced, it has a major drawback: the tensile force required to achieve closure with sutures or staples causes very high localized stresses at the suture insertion points, resulting in the rupture of the tissue at these points. Substantial rupture will eventually cause dehiscence in some wounds, which results in additional tissue loss. Moreover, some infected wounds harden and inflame to such a degree that closure by suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalizations with its attendant high costs, and major surgical procedures, such as grafts of surrounding tissue. Examples of such wounds include large, deep, open wounds, pressure sores resulting from prolonged pressure, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

To date, there has been no consistently satisfactory method for treating such wounds. What is needed is a method of closing the wound without the localized stresses that accompany suturing while at the same time treating any infection present in the wound along with a simple apparatus to carry out the method. Such a method and apparatus would reduce hospitalization and increase the probability of wound closure.

WO-A-90/11795 relates to a fluidic connection system for wound drainage or fluid introduction. The device comprises a cover membrane which overlies a wound. The proximate end of a tube fluidically communicates with the wound through an opening in the cover membrane. The device can be operated to evacuate or introduce fluids in either an active or a passive manner. When operated in an active mode, the distal end of the tube is connected to a suction source for draining the wound or to a fluid source for introducing fluid into the wound.

<>

Summary of the Invention

The invention provides an apparatus for facilitating the healing of a wound according to claim 1. The ~~A preferred~~ embodiment of the invention comprises an open-cell polymer foam section configured to overlie a wound, and a flexible tube having an inlet end and an outlet end, said inlet end being inserted into said open cell polymer foam section. A flexible polymer sheet may overly the foam section and tubing and be configured to be adhered to the skin surrounding the wound.

The invention will now be further described, by way of example, with reference to the accompanying drawings, in which:

Brief Description of the Drawings

Figure 1 shows a cross-sectional view of a negative pressure device comprising a open-cell polymer screen, a flexible hose connecting the foam section to a suction pump, and a flexible polymer sheet overlying the foam-hose assembly to provide the necessary seal; and

Figure 2 shows a cross-sectional view of a negative pressure device comprising a porous screen, an inflatible cuff attached to a semi-rigid cup, and a flexible hose extending from a suction pump to a point within the sealed volume of the cup-cuff assembly.

Detailed Description of the Invention

The present invention relates to an apparatus for treating tissue damage according to claim 1. Wound closure

< M.E. Chariker et al, in Contemporary Surgery, Vol 34, June 1989, pages 59-63 relates to an apparatus providing closed suction wound drainage. >

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requires that epithelial and subcutaneous tissue migrate from the wound border toward the wound. The use of negative pressure provides tension on this border tissue that causes accelerated tissue migration. It has been observed that the use of the apparatus also causes within the wound increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing.

Apparatus according to the invention is particularly suited for use on pressure sores. A pressure sore is a wound that develops due to constant compressive pressure on the skin surface and underlying tissue. Blood flow to the compressed tissue is restricted to the extent that the overlying tissue dies and subsequently allows the underlying tissue to become infected. The decrease of blood flow to the wound prevents a normal immune reaction to fight the infection, the presence of which prevents tissue migration from the wound border. Pressure sores often occur on bedridden patients who are unable to feel the sore or to move sufficiently to relieve the contact pressure. Such wounds can become very serious, requiring extensive and repeated skin grafts; some are even fatal. As described above, application of negative pressure to the sore permits migration of wound border tissue to occur and thus allows sores to heal without these more drastic procedures.

The invention can be practiced with the application of substantially continuous negative pressure, where the pressure is relieved only to change the dressing on the wound, or it can be practiced with the use of a cydic application of pressure in alternate periods of application and non-application. The ratio of duration of application period to non-application period can be as low as 1:10 or as high as 10:1, but is most preferably 1:1. A preferred pattern is 5 minutes of pressure application followed by 5 minutes of relief.

The invention is practiced using a negative pressure ranging from ~~10.1~~ 1.01 and 100.3 kPa (0.01 to 0.99 atmospheres) and more preferably practiced using a negative pressure ranging between 50.7 and 81.1 kPa (0.5 to 0.8 atmospheres). The time period for use of the method on a wound is preferably at least 12 hours, but can be, for example, 1 day, 2 days, 5 days, 7 days, 14 days, 30 days, or even longer. There is no upper limit beyond which use of the method is no longer beneficial; the method increases the rate of closure up to the time the wound actually closes.

Open wounds are almost always contaminated with harmful bacteria. Generally a bacterial density of 10^5 bacterial organisms per gram of tissue is regarded as infected. (It is generally accepted that at this level of infection, grafted tissue will not adhere to a wound). These bacteria must be killed, either through the wound host's natural immune response or through some external method, before a wound will close. We have observed that application of negative pressure to a wound will reduce the bacterial density of the wound; it is believed that this effect is due to either the bacteria's incompatibility with a negative pressure environment or the increased blood flow to the wound area, as blood brings with it cells and enzymes to destroy the bacteria.

The invention can be used to reduce bacterial density in a wound by at least half. More preferably, it can be used to reduce bacterial density by at least 1,000 fold. Most preferably, the method can be used to reduce bacterial density by at least 1,000,000 fold. The ranges of pressure magnitude and application duration are as described above, although Example 3 demonstrates dramatic reduction in wound contamination after a 4-day application of negative pressure. Pressure can be applied continuously or cyclically in the application/nonapplication ratios described above.

The present invention may also be used for treating a burn. A partial thickness burn, one which has a surface layer of dead tissue and an underlying zone of stasis, is often sufficiently infected that it will transform within 24-48 hours into a full thickness burn, one in which all epidermal structures are destroyed. As explained above, the application of a negative pressure to the wound prevents the infection from becoming sufficiently severe to cause destruction of the underlying epidermal structures. As above, the magnitude, pattern, and duration of pressure application can vary with the individual wound.

The present invention also serves to enhance the attachment of living tissue to a wound. Attachment of living tissue to a wound is a common procedure that can take many forms. For example, one common technique is the use of a "flap", a technique in which skin tissue from an area adjacent to the wound is detached on three sides but remains attached on the fourth, then is moved onto the wound. Another frequently used technique is an open skin graft in which skin is fully detached from another skin surface and grafted onto the wound. The application of negative pressure to the wound-graft complex reduces bacterial density in the complex and improves blood flow to the wound, thereby improving the attachment of the grafted tissue.

The acceptable ranges of time, magnitude, and application/non-application ratio are as described above. Each of these variables is affected by the size and type of wound.

Apparatus according to the present invention for facilitating the healing of wounds comprises vacuum means such as a pump for creating a negative pressure on the area of skin surrounding the wound, sealing means such as an adhesive sheet operatively associated with the vacuum means for maintaining negative pressure on the wound by contacting the skin surrounding the wound, and screen means such as an open-cell foam section located within the sealing means for preventing the overgrowth of tissue in the wound area.

The screen means is placed over substantially the expanse of the wound to prevent its overgrowth. The size and configuration of the screen can be adjusted to fit the individual wound. It can be formed from a variety of porous semi-rigid materials. The material must be sufficiently porous to allow oxygen to reach the wound, and sufficiently rigid to pre-

The screen means comprises 9 dec. 2003

vent wound overgrowth. ~~Most preferred is the use of~~ an open-cell polymer foam, which permits direct connection of the screen means to the vacuum means through a flexible hose inserted into the foam. Such foam can vary in thickness and rigidity, although it is preferred that a spongy material be used for the patient's comfort if the patient must lay upon the device during its operation. It can also be perforated to reduce its weight. Another embodiment comprises a section of honeycombed polyethylene sheet cut to the shape of the wound.

Possible sealing means include a flexible sealing rim contacting the skin surrounding the wound, a flexible polymer sheet overlying the screen means and the vacuum means and attached to the skin through an adhesive applied to the sheet surface facing the skin, and an inflatable sealing cuff that conforms to the skin when inflated and that is held in place by the suction of the vacuum means. If an adhesive sheet is used, it must have sufficient adhesion to remain in contact with the skin and form a seal under the negative pressure. Additionally, it must be sufficiently flexible to overlay the screen means and still conform to the skin around the wound. The sealing means also can include a semi-rigid cup that protects the wound from external contact. For example, a suitable cup-cuff assembly is provided by an adult CPR mask with an inflatable sleeve.

Suitable vacuum means includes any suction pump capable of providing at least 689.5 Pa (0.1 psi) suction to the wound, and preferably up to 20.7 kPa (3 psi) suction, and most preferably up to 96.5 kPa (14 psi) suction, and a flexible hose that leads from the pump to a point within the pressurized volume created by the sealing means. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the necesary suction. The dimension of the tubing are limited only by the pump's ability to provide the suction level neede for operation. A 6.4 mm (1/4 inch) diameter tube has proven suitable. The vacuum means may operate substantially continuously, or may operate cyclically with alternate periods of application and nonapplication of pressure to the wound.

A preferred embodiment of the invention, shown in Figure 1, comprises a substantially flat section of open cell polyester foam section 10 (Fischer Scientific, Pittsburgh, PA 15219) sufficiently large to cover the wound and thus prevent wound overgrowth, a flexible hollow tube 11 (Fischer Scientific) inserted into the open cell foam section 10 and joined thereto with an adhesive and extending to attach at its opposite end to a Cast Vacuum pump (Fischer Scientific), and an loban adhesive sheet 12 (Minnesota Mining and Manufacturing, St. Paul, MN. 55144) overlying the foam section 10 and tubing 11 and adhered to the skin surrounding the wound, thus forming a seal that allows creation of a vacuum when the suction pump operates. Such an apparatus would most preferably be packaged in a sterile condition to ameliorate the need for sterilization of the apparatus prior to use (note that the adhesive sheet 12 could be packaged separately from the foam-tube assembly). A particular advantage of this configuration is its use with pressure sores: the device can be placed in the depths of the wound and the patient can lie upon it without either affecting the utility of the device or further damaging the wound. This becomes critical if the patient cannot be moved from this posture for other medical reasons.

The present invention is explained further in the following examples. These examples are provided for illustrative purposes only and are not to be taken as limiting.

EXAMPLE 1

Rate of Wound Healing under Negative Pressure

This example demonstrates the use of negative pressure to increase the rate of healing of full thickness defects by increasing vascularity and the amount of granulation tissue present.

Fifteen-kilogram pigs were obtained and conditioned for 1 week prior to use. The backs of the pigs were shaved and scrubbed for surgery. Two full thickness circular defects were created on the midline of the animals, 2.5 cm in diameter and 1 cm thick. Alginate impressions were taken of each defect to determine its volume. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). The suction devices used, shown in Figure 2, comprised an adult CPR mask 20 (Doug Brown and Associates, Huntington Beach, CA 92648) comprising a semi-rigid cup 21 and inflatible cuff 22 in contact with the skin, an open cell polyester screen 24 overlying the wound, and a flexible 6.4 mm (1/4 inch) diameter hose 23 (Fischer Scientific) connected by a Nalgene tubing connector to a vacuum pump (Fischer Scientific) and extending through a sealed hole in the cup. Each device was configured such that the suction hose ran from the cup on the animal up through a pulley suspended over the center of the pen and down to a vacuum trap bottle to collect any liquid exudate, then down to the vacuum pump. A suction device was attached over each defect, and suction of 13.8 to 41.4 kPa (2-6 psi) was applied to one of the devices. The devices were removed only so that impressions could be made of each defect. This procedure was continued until the volume of both defects was zero.

Table 1 shows data expressed as the amount of granulation tissue formed per day and as the percent difference in rate of granulation tissue formation. The data shows that in all cases the use of negative pressure increased the rate of wound closure and the formation of granulation tissue at a statistically significant rate.

EXAMPLE 2

Rate of Burn Healing under Negative Pressure

This example was designed to demonstrate the use of continuous closed suction for the treatment of deep, partial thickness thermal burns (second degree burns).

The backs of 15 kg pigs were shaved and scrubbed for surgery. A 38 mm (1.5 inch) diameter brass rod was heated to 190°C in an oil bath. The rod was pressed onto the pig's skin for 15 seconds following a well-known technique of relating depth of burn to time and temperature. Three burns were created over the spine of each pig, separated by 5 cm intervals. Suction apparatus cups of the configuration described above were placed over two of the burns, with silver sulphadiazine (Silvadine) cream, the standard antibiotic cream applied to human burns prior to excision of burned tissue, applied to the third. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). Suction of 13.8 to 41.4 kPa (2-6 psi) was applied to one of the cups. A small (2 mm) punch biopsy was taken of the wounded area and examined histologically for depth of burn.

Table 1

Rate of granulation tissue formation for control and reduced pressure treated full thickness defects in pigs.

Animal	Granulated Treatment	Tissue/Day (cc)	% Increase*
1	Suction	0.48	26.3
	Control	0.38	
2	Suction	1.16	28.9
	Control	0.90	
3	Suction	0.58	75.8
	Control	0.33	
4	Suction	0.71	65.1
	Control	0.43	
5	Suction	0.71	65.1
	Control	0.43	

* (Suction-Control)/Control

Table 2

Rate of reduction in bacterial density for control and reduce and pressure treated pigs (n=5).

treatment	Log Organisms Per Gram Tissue							
	Day 0		Day 1	Day 2	Day 3	Day 4	Day 5	Day 7
control	Mean	8.44	8.04	8.17	7.13	7.13	8.82	7.08
	SD	+.38	±.13	±.98	±.15	±.24	±1.12	±.52
vacuum	Mean	7.69	7.36	7.37	6.79	6.43	3.98	4.32
	SD	±.83	±.84	±1.40	±.55	±.45	±3.46	±3.74

Biopsies were analyzed by a dermatopathologist who was not told the nature of the study. It was concluded that the suctioned tissue specimens were healthier and healing more quickly than non-suctioned specimens.

EXAMPLE 3

Reduction of Bacterial Density under Negative Pressure

This example illustrates the effects of continuous closed suction on the bacterial density of infected tissue.

Fifteen-kilogram pigs were shaved and prepared for surgery. Two 2.5 cm diameter defects were created on the dorsum of each pig using sterile technique, with a 7.5 cm interval retained between the edges of the defects. Hemostasis was obtained by electrocautery. One ml of culture broth containing 10^8 Staph. aureus organisms was injected just beneath the surface tissue in the center of each wound. Suction cups of the configuration described above were placed over each defect, and a T-shirt was placed over the animal. Suction of 13.8 to 41.4 kPa (2-6 psi) was applied 24 hours after surgery to only one of the defects, allowing each animal to act as its own control. No antibiotics were given during the course of the study.

Each day, a small (3 mm biopsy punch) piece of granulation tissue was removed from the center of each defect. The number of organisms present in the tissue was determined by weighing the tissue, homogenizing the tissue, serially diluting the supernatant, and plating the diluted supernatant on blood agar plates. Samples of the original broth were treated in an identical manner to determine effects of mechanical manipulations on bacteria viability. The procedure was performed until the wounds were healed.

Table 2 compares the bacterial density of treated wounds and control wounds over time. The data is expressed as the mean log of the number of viable organisms per gram of tissue as a function of time. Clearly, the application of negative pressure increases the rate at which bacteria are destroyed. Using 10^5 organisms per gram of tissue as a baseline for infection, the data show that on average a suctioned wound was disinfected after 4 days of treatment, while the average non-treated wound was still infected after 7 days.

EXAMPLE 4

Treatment of Pressure Sore With Negative Pressure

Mr. L.J. is a 45-year-old diabetic male who has been a paraplegic as the result of a gunshot wound for 12 years. He has a history of recurrent right ischeal fossa pressure sore and right trochanteric pressure ulcer. L.J. was admitted to the hospital for treatment and closure of the pressure sores. A flap was placed onto the wound and secured with sutures and staples.

The incisions of the flap dehisced, resulting in a large, open wound. The tissues of the flap were very edematous and indurated. Nine days after the flap was detached, a negative pressure device was placed over the wound. The device comprised an open-cell polyester foam section (Fischer Scientific) approximately 12.7 mm (1/2 inch) in thickness attached to a suction pump by a flexible hose (Fischer Scientific) and covered and sealed by loban polymer sheet (Minnesota Mining and Manufacturing, St. Paul, MN 55144). A continuous vacuum of 34.5 kPa (5 psi) was applied to the wound. The design of the device allowed the patient to lay comfortably on the device during operation.

The depth of the wound decreased dramatically. The devices were changed and the wound examined on a three times per week basis. Reduced pressure treatment was continued for 6 weeks, at which time the wound was healed.

EXAMPLE 5

Treatment of Pressure Sore With Negative Pressure

Mr. W.E. is a 51-year-old male who had both legs amputated at the hip approximately 20 years ago. He was afflicted with a large pressure sore in the buttocks region. The pressure sore had been present 7 months and measured 200 mm (8 inches) laterally and 76 mm (3 inches) in its greatest width. An open cell foam reduced pressure device as described in Example 4 was placed over the wound and a negative pressure of 34.5 kPa (5 psi) was applied cyclically in alternate periods of 5 minutes on, 5 minutes off. The open cell foam device was used as the patient was lying on the device. The device was changed on a three times per week schedule.

After 5 weeks of treatment, the wound measured 76mm (3 inches) laterally and 38 mm (1.5 inches) at its greatest width. At that point the wound was essentially healthy granulation tissue that accepted a cultured keratinocyte allograft and healed completely.

EXAMPLE 6

Treatment of Wound Dehiscence With Negative Pressure

Mr. C.L. is a 50-year-old male who had undergone a colostomy revision through a midline laparotomy. He was readmitted to the hospital for wound dehiscence and evisceration following forceful coughing. The abdominal wall was closed with Prolene mesh coverage. Six weeks after placement of the Prolene mesh, the wound was still open and measured 28 cm by 23 cm with sparse granulation tissue grown through the Prolene mesh. A large reduced pressure cup device of the type described in Example 1 with an underlying porous Aquaplast sheet (WFR/Aquaplast Corp., Wyckoff, NJ 07481) was placed on the Prolene mesh/wound surface and the space closed with a tent of loban. 34.5 kPa (5 psi) of continuous negative pressure was applied. The device was changed three times per week.

After 6 days, granulation tissue had grown through the Prolene mesh, totally covering the mesh. The patient was taken to the operating room where the surrounding tissue was undermined and grafted onto the wound to partially close the defect. Split thickness skin grafts were used to cover the remainder of the defect, and were placed on the bed of granulation tissue. The wound accepted 80 % of the grafts, and the remaining areas closed with dressing changes alone.

EXAMPLE 7

Treatment of Ankle Osteomyelitic Ulcer With Negative Pressure

Mr. R.F. is a 39-year-old white male who had severe trauma to his left lower extremity secondary to a motor vehicle accident 10 years ago. He had contracted chronic osteomyelitis and an open ulcer with exposed bone of his left lateral ankle (lateral malleolar ulcer). Necrotic soft tissue and bone were surgically removed from the ankle. The patient was placed on a 2-1/2 week course of antibiotics. The day after surgery, a reduced pressure device of the type described in Example 1 was placed over the wound, and a negative pressure of 34.5 kPa (5 psi) was applied. The device was changed on a three times per week schedule. After 14 days of treatment, the wound was smaller and filled with granulation tissue. A split thickness skin graft was placed over the center of the defect and healed primarily.

EXAMPLE 8

Treatment of Burn With Negative Pressure

Patient B. is admitted with second and third degree burns over the face and upper extremities, including both hands, as a result of a house fire. A large mitten-shaped reduced pressure device of the type described in Example 4 is placed over the patient's right hand, with open cell foam inserts placed between the fingers to apply reduced pressure to the interdigit spaces. A vacuum of 20.7 kPa (3 psi) is applied cyclically in a pattern of 5 minutes on, 5 minutes off. The device is changed on a three times per week schedule. Treatment is continued until the necrotic tissue sloughs off or is excised, followed by split thickness skin graft placement.

The foregoing examples are illustrative of the present invention, and are not to be construed as limiting thereof. The invention is defined by the following claims, with equivalents of the claims to be included therein.

Claims

1. An apparatus for facilitating the healing of a wound, comprising vacuum means (11,23) for creating a negative pressure on the area of the skin including and surrounding the wound and sealing means (12,20) operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound, characterised in that said negative pressure is between about 10.1 and 100.3 kPa (0.1 and 0.99 atmospheres) and in that said apparatus comprises screen means (10,24) for positioning at the wound within the sealing means for preventing overgrowth of tissue at the wound.

2. An apparatus according to claim 1, in which said screen means (10,24) comprises an open-cell polymer foam.

3. An apparatus according to claim 1, in which said screen means (10, 24) comprises a flat, porous, semi-rigid member.

4. An apparatus according to claim 1, 2, or 3, in which said sealing means (12,20) includes a flexible sealing rim in contact with said skin surrounding said wound.

5. An apparatus according to claim 1 or 2 in which said sealing means (12) includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin.

6. An apparatus according to claim 1 or 3, in which said sealing means (20) includes a semi-rigid cup (21) configured to protect said wound from external contact.

7. An apparatus according to claim 6, in which said sealing means (20) includes a sealing cuff (22) in contact with said skin surrounding the wound.

8. An apparatus according to claim 7, in which said sealing cuff (22) is inflatable.

9. An apparatus according in to claim 1, which includes an open-cell foam section (10) configured to overlie the wound, and in which said sealing means (12) includes a fluid-impermeable flexible cover overlying said foam section, said cover adapted to form a seal with skin surrounding the wound for maintaining negative pressure beneath said cover, and in which said vacuum means (11) includes a single tubular member having a first end inserted beneath at least a portion of the foam section (10) and having a second end extending from said cover to a location external to said cover for supplying negative pressure beneath the cover.

10. An apparatus according to claim 9, in which said first end of the tubular member (11) is inserted within the foam section (10).

11. An apparatus according to claim 1, in which said sealing means (20) includes:

a) a semi-rigid, fluid-impermeable cup (21) for positioning over the wound and for maintaining a negative pressure upon said wound, said cup (21) having only a single external fluid communication port; and
b) seal means for sealing said cup about the wound, said seal means including a cuff (22) for inflating and conforming to the surrounding skin to seal said cup (21) in place by said negative pressure;
and wherein said vacuum means (23) is connected with said fluid communication port of said cup (21) for supplying said negative pressure.

12. An apparatus according to claim 11, which comprises screen means for positioning beneath the cup at the wound for preventing overgrowth of the wound.

13. An apparatus according to any one preceding claim, in which said vacuum means (11,23) includes pump means capable of providing at least 689.5 Pa (0.1 psi) suction.

14. An apparatus according to any one of claims 1 to 12, in which said vacuum means (11,23) includes a pump means capable of providing at least 20.7 kPa (3 psi) suction.

15. An apparatus according to any one of claims 1 to 12, in which said vacuum means (11,23) includes a pump means capable of providing at least 96.5 kPa (14 psi) suction.

16. An apparatus according to any one preceding claim, in which said vacuum means (11,23) operates continuously.

17. An apparatus according to any one of claims 1 to 15, in which said vacuum means (11,23) operates cyclically to provide periods of application and non-application of suction.

18. An apparatus according to claim 1 wherein the screen means (10) includes an open cell polymer foam section configured to overlie the wound; and wherein the vacuum means (11) includes a flexible tube having an inlet end an outlet end, said inlet end being inserted into said open cell polymer foam section (10).

19. An apparatus according to claim 18, which is in an aseptic package.

20. The apparatus according to claim 17, wherein said vacuum means (11,23) operates cyclically to provide periods of application and non-application of suction with the ratio of duration of application period to non-application period between about 1:10 and 10:1.

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Claims (Fifth Auxiliary Request)

1. An apparatus for facilitating the healing of a wound, comprising vacuum means (11,23) for creating a negative pressure on the area of the skin including and surrounding the wound and sealing means (12,20) operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound, characterised in that said negative pressure is between about 1.01 and 100.3 kPa (0.01 and 0.99 atmospheres) and in that said apparatus comprises screen means (10,24) for positioning at the wound within the sealing means for preventing overgrowth of tissue at the wound [,]

~~2. An apparatus according to claim 1~~ [in which said screen means (10,24) comprises an open-cell polymer foam.]

2. An apparatus according to claim 1, in which said screen means (10, 24) comprises a flat, porous, semi-rigid member.

3. An apparatus according to claim ~~1~~ or 2 ~~or 3~~, in which said sealing means (12,20) includes a flexible sealing rim in contact with said skin surrounding said wound.

4. An apparatus according to claim 1 ~~or 2~~ in which said sealing means (12) includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin.

5. An apparatus according to claim 1 or 2, in which said sealing means (20) includes a semi-rigid cup (21) configured to protect said wound from external contact.

6. An apparatus according to claim 5, in which said sealing means (20) includes a sealing cuff (22) in contact with said skin surrounding the wound.

7. An apparatus according to claim 6, in which said sealing cuff (22) is inflatable.

8. An apparatus according in to claim 1 which ~~includes a~~ the open-cell foam section (10) is configured to overlie the wound, and in which said sealing means (12) includes a fluid-impermeable flexible cover overlying said foam section, said cover adapted to form a seal with skin surrounding the wound for maintaining negative pressure beneath said cover, and in which said vacuum means (11) includes a single tubular member having a first end inserted beneath at least a portion of the foam section (10) and having a second end extending from said cover to a location external to said cover for supplying negative pressure beneath the cover.

9. An apparatus according to claim 8, in which said first end of the tubular member (11) is inserted within the foam section (10).

10. An apparatus according to claim 1, in which said sealing means (20) includes:

a) a semi-rigid, fluid-impermeable cup (21) for positioning over the wound and for maintaining a negative pressure upon said wound, said cup (21) having only a single external fluid communication port; and
b) seal means for sealing said cup about the wound, said seal means including a cuff (22) for inflating and conforming to the surrounding skin to seal said cup (21) in place by said negative pressure;
and wherein said vacuum means (23) is connected with said fluid communication port of said cup (21) for supplying said negative pressure.

11. An apparatus according to claim 10, which comprises screen means for positioning beneath the cup at the wound for preventing overgrowth of the wound.

12. An apparatus according to any one preceding claim, in which said vacuum means (11,23) includes pump means capable of providing at least 689.5 Pa (0.1 psi) suction.

13. An apparatus according to any one of claims 1 to 12, in which said vacuum means (11,23) includes a pump means capable of providing at least 20.7 kPa (3 psi) suction.

14. An apparatus according to any one of claims 1 to 12, in which said vacuum means (11,23) includes a pump means capable of providing at least 96.5 kPa (14 psi) suction.

15. An apparatus according to any one preceding claim, in which said vacuum means (11,23) operates continuously.

16 17. An apparatus according to any one of claims 1 to 14, in which said vacuum means (11,23) operates cyclically to provide periods of application and non-application of suction.

17 18. An apparatus according to claim 1 wherein the screen means (10) includes an open cell polymer foam section configured to overlie the wound; and wherein the vacuum means (11) includes a flexible tube having an inlet end an outlet end, said inlet end being inserted into said open cell polymer foam section (10).

18 19. An apparatus according to claim 17, which is in an aseptic package.

19 20. The apparatus according to claim 16, wherein said vacuum means (11,23) operates cyclically to provide periods of application and non-application of suction with the ratio of duration of application period to non-application period between about 1:10 and 10:1.

~~21. An apparatus according to any preceding claim wherein said vacuum means (11,23) supplies a negative pressure between about 50,7 and 100,3 kPa (0.5 and 0.99 atmospheres) to the wound.~~

20 22. An apparatus according to any one preceding claim wherein said vacuum means (11,23) supplies a negative pressure between about 50,7 and 100,3 kPa (0.5 and 0.99 atmospheres) to the wound.

21 23. An apparatus according to any one preceding claim wherein said vacuum means (11,23) supplies a negative pressure between about 50,7 and 81,1 kPa (0.5 and 0.8 atmospheres) to the wound.

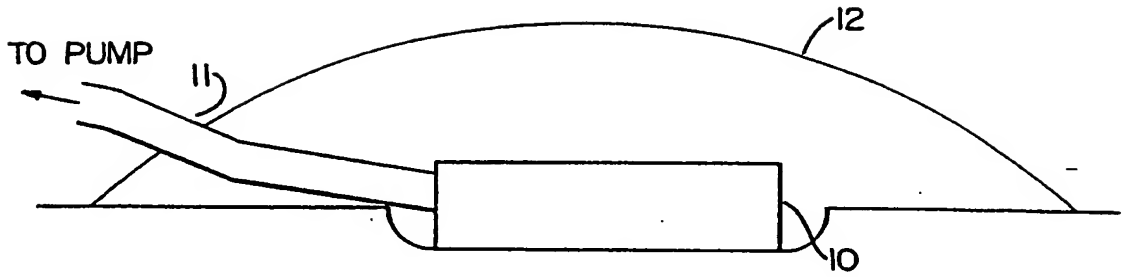

FIG. 1.

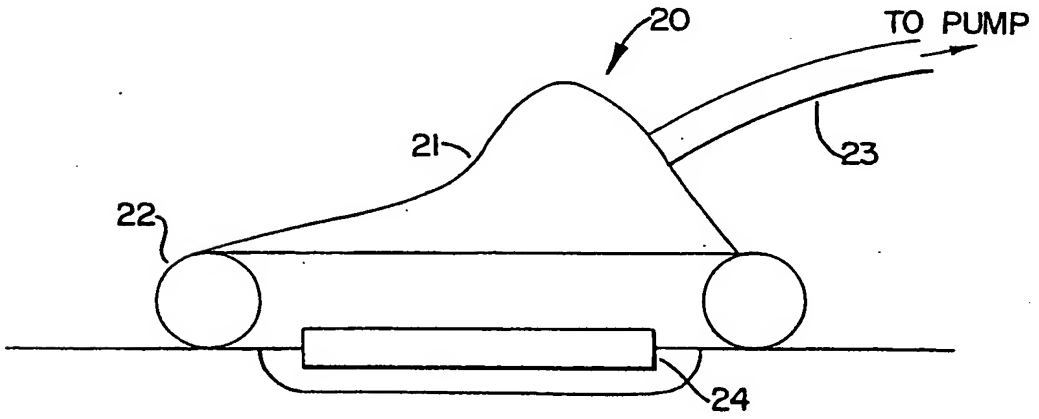

FIG. 2.